UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GUNTER CROMMELIN, Individually and on Behalf of All Others Similarly Situated,	)	**Case No. 1:24-cv-10552**
Plaintiff,	)	**DEMAND FOR JURY TRIAL**
vs.	)	
TAKEDA PHARMACEUTICALS U.S.A., INC.; TAKEDA PHARMACEUTICALS AMERICA, INC.; and TAKEDA MANUFACTURING U.S.A., INC.,	)	**COMPLAINT – CLASS ACTION**
Defendants.	)	

CLASS ACTION COMPLAINT

Plaintiff Gunter Crommelin ("Plaintiff"), individually and on behalf of all others similarly situated, files this Class Action Complaint against Defendants Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., and Takeda Manufacturing U.S.A., Inc. (collectively, "Defendants" or "Takeda"). In support, she states and alleges as follows:

INTRODUCTION

1. This case arises from the manufacture and sale of prescription medicine Vyvanse (lisdexamfetamine dimesylate), which is used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) in children and adults, age six or older, as well as Binge Eating Disorder (B.E.D.) in adults. According to its website, Vyvanse is the first and only approved treatment for moderate to severe B.E.D. in adults. *See Binge Eating Disorder in Adults*, VYVANSE, https://www.vyvanse.com/binge-eating-disorder (last visited Feb. 2, 2024). Vyvanse purports to be the #1 prescribed branded ADHD medication, treating millions of lives since 2007. *See ADHD in Children*, VYVANSE, https://www.vyvanse.com/adhd-in-children (last visited Feb. 2, 2024).

2. Plaintiff had a prescription for 40 mg Vyvanse capsules, which she used to treat her ADHD. She filled her prescription on September 12, 2023. Plaintiff learned that a friend of hers had received empty capsules after filling her Vyvanse prescription. Plaintiff's friend advised Plaintiff to check her Vyvanse capsules, too. Plaintiff opened her Vyvanse capsules and discovered that her capsules were also empty. Online research revealed that many others were complaining of the same problem with their prescribed Vyvanse medication.

3. Around this time, there had been disruptions in the supply chain of Vyvanse and other ADHD medications. *See* Christina Caron, *The Collateral Damage of A.D.H.D. Drug Shortages*, THE N.Y. TIMES (Aug. 28, 2023), https://www.nytimes.com/2023/08/15/well/mind/adhd-adderall-shortage-children.html ("A representative from Takeda Pharmaceuticals, which makes Vyvanse, said in an email that a 'manufacturing delay, which we are actively working to resolve,' had created a temporary disruption in the supply of certain Vyvanse capsules, adding that 'we expect this to continue into September 2023.'"); Ike Swetlitz, *ADHD Drug Shortage Set to Ease as Generic Vyvanse Approved*, BLOOMBERG (Aug. 25, 2023), https://news.bloomberglaw.com/health-law-and-business/adhd-drug-shortage-set-to-ease-as-generic-vyvanse-approved (noting an increase in Vyvanse demand due to a shortage in generic Adderall and mentioning a shortage in Vyvanse "since June" 2023 due to "problems at a contracted manufacturing facility").

4. The shortage of ADHD medications became so severe that the FDA asked manufacturers to increase production and meet their allotted quota amount. Letter from Robert M. Califf, M.D., FDA Commissioner (Aug. 1, 2023), *available at* https://www.fda.gov/media/170736/download.

5. Amidst this shortage, consumers, like Plaintiff, who believed they were obtaining medication to treat their ADHD were in fact receiving empty capsules or capsules containing less of the active ingredient than indicated.

6. As a result, Plaintiff brings this action on behalf of those consumers who lost money or were otherwise injured by Takeda's empty, or partially empty, Vyvanse capsules.

PARTIES

7. Plaintiff Gunter Crommelin is an individual and resident of Jefferson County, Alabama.

8. Defendant Takeda Pharmaceuticals U.S.A., Inc. is a foreign corporation existing under the laws of the State of Delaware with its principal place of business at 95 Hayden Avenue, Lexington, Massachusetts 02421.

9. Defendant Takeda Pharmaceuticals America, Inc. is a foreign corporation existing under the laws of the State of Delaware with its principal place of business at 95 Hayden Avenue, Lexington, Massachusetts 02421.

10. Defendant Takeda Manufacturing U.S.A., Inc. is a foreign corporation existing under the laws of the State of Delaware with its principal place of business at 95 Hayden Avenue, Lexington, Massachusetts 02421.

JURISDICTION AND VENUE

11. This Court has jurisdiction over all causes of action asserted herein pursuant to 28 U.S.C. § 1332(d) because this is a class action with diversity of citizenship between parties and the matter in controversy exceeds $5,000,000.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants reside in this District and are subject to this Court's personal jurisdiction.

GENERAL ALLEGATIONS

Takeda Is Required to Follow Strict Federal Regulations Before Warranting Its Drug as Safe and Effective

13. The federal government has implemented a strict regulatory framework that drug manufacturers must follow before putting their drugs into the marketplace. Unsurprisingly, drug manufacturers are required to accurately label their drugs with, among other things, a quantitative description of the active ingredients.

14. Consumers expect that their drugs will conform to these federal regulations and be safe and effective.

15. Plaintiff references federal law in this Complaint not in any attempt to enforce it, but to demonstrate that her state-law claims do not impose any additional obligations on Takeda, beyond what was already required of it under federal law. Plaintiff is not bringing any claims pursuant to federal law.

Adulterated and Misbranded Drugs

16. The manufacture and sale of any adulterated or misbranded drug is prohibited under federal law. *See* 21 U.S.C. § 331(g).

17. The introduction into commerce of any adulterated or misbranded drug is also prohibited. *See* 21 U.S.C. § 331(a).

18. Among the ways that a drug may be adulterated are:

a. "[I]f it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health[.]"

b. "[I]f . . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not

operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess[.]"

c. "If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium."

21 U.S.C. § 351.

19. Among the ways that a drug may be misbranded are:

a. "If its labeling is false or misleading in any particular."

b. "If in package form unless it bears a label containing . . . an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count . . . ."

c. If the labeling does not contain "the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient . . . ."

d. "Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. . . . "

e. "If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein."

f. "If it is a drug and its container is so made, formed, or filled as to be misleading . . . ."

g. "If it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

h. If advertisements lack "a true statement of . . . the formula showing quantitatively each ingredient of such drug . . . and such other information in brief summary relating to . . . effectiveness . . . ."

i. If the drug's "packaging or labeling is in violation of an applicable regulation . . . ."

21 U.S.C. § 352.

20. As alleged herein, the Vyvanse capsules sold to Plaintiff and putative class members were adulterated and/or misbranded in violation of 21 U.S.C. §§ 331, 351, 352.

Requirements for Labeling

21. A manufacturer is required to give adequate directions for the use of a pharmaceutical drug such that a "layman can use a drug safely and for the purposes for which it is intended," and conform to requirements governing the appearance of the label. *See* 21 C.F.R. §§ 201.5.

22. "Directions for use may be inadequate" if the "quantity of dose" is incorrectly specified. *See* C.F.R. § 201.5(b).

23. The labeling may also be misleading if it does not reveal "the proportion of, or other fact with respect to, an ingredient present in such drug, when such proportion or other fact is

material in the light of the representation that such ingredient is present in such drug." *See* C.F.R. § 201.10(c)(2).

24. "If the drug is in tablet or capsule form or other unit dosage form, any statement of the quantity of an ingredient contained therein shall express the quantity of such ingredient in each such unit." *See* C.F.R. § 201.10(d)(1).

25. Prescription labels for drug capsules are required to have an accurate statement as to the quantity of each active ingredient. *See* 21 C.F.R. § 201.51.

26. Because Plaintiff's Vyvanse was represented as being 40 mg but was in fact 0 mg, the subject drugs were misbranded.

27. It is unlawful to manufacture and sell misbranded drugs or otherwise introduce them into interstate commerce. *See* 21 U.S.C. § 331(a), 331(g).

Current Good Manufacturing Practices ("cGMPs")

28. Under federal law, pharmaceutical drugs must be manufactured in accordance with "current Good Manufacturing Practices" ("cGMPs") to ensure they meet safety, quality, purity, identity, and strength standards. *See* 21 U.S.C. § 351(a)(2)(B). Takeda violated cGMPs in the manufacture of Vyvanse, including the failure to ensure that Vyvanse met required safety, quality, purity, and identity standards, both under state and federal law.

29. 21 C.F.R. § 210.1(a) states that the cGMPs establish "minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess."

30. The FDA's cGMPs regulations are found in 21 C.F.R. Parts 210 and 211 and set forth minimum standards applicable to any facility manufacturing drugs intended to be distributed in the United States.

31. Any drug not manufactured in accordance with cGMPs is deemed adulterated and/or misbranded and may not be distributed or sold in the United States. *See* 21 U.S.C. §§ 331(a), 351(a)(2)(B). States have enacted laws adopting or mirroring these federal standards.

32. The cGMPs necessary to ensure that a product is not adulterated and/or misbranded require "the implementation of oversight and controls over the manufacture of drugs to ensure quality, including managing the risk of and establishing the safety of raw materials, materials used in the manufacturing of drugs, and finished drug products." 21 U.S.C. § 351(j).

33. FDA regulations require a "quality control unit" to independently test drug products being manufactured. *See* 21 C.F.R. § 211.22. FDA regulations require drug manufacturers to have "written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 C.F.R. § 211.100.

34. A drug manufacturer's "[l]aboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity." 21 C.F.R. § 211.160(b).

35. "Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays" within which must be a "statement of the results of tests and how the results compare with

established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested." 21 C.F.R. § 211.194(a).

36. If Takeda had not disregarded reasonable and safe manufacturing practices, quality processes, and cGMPs, including those discussed herein, Takeda could have prevented the manufacture and distribution of Vyvanse capsules containing inadequate doses of lisdexamfetamine dimesylate.

37. 21 C.F.R. § 211.110 contains the cGMPs regarding the "Sampling and testing of in-process materials and drug products". Subsection (c) states the following:

> In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

21 C.F.R. § 211.110(c). This requirement was violated by Takeda. If these sampling-related and quality-control-related cGMPs were properly observed by Takeda, the manufacture and distribution of empty, or partially empty, Vyvanse capsules would have been prevented.

38. Plaintiff and putative class members suffered direct economic loss, among other damages, as a result of purchasing medication that lacked the adequate prescribed dosage. These medications were worthless and illegally sold to Plaintiff and putative class members.

Takeda Breached Express Warranties to Plaintiff and Putative Class Members

39. Takeda made and breached express warranties to consumers about its adulterated and/or misbranded Vyvanse capsules.

40. Consumers, including Plaintiff, are natural persons who are reasonably expected to use, consume, or be affected by the adulterated and/or misbranded Vyvanse manufactured and sold by Takeda.

41. Drug manufacturers, such as Takeda, contract directly with wholesalers and retail pharmacies for the sale of pharmaceutical products, and Plaintiff and putative class members are the intended third-party beneficiaries of these contracts, including all representations and warranties provided.

42. Takeda proudly markets itself as putting the patient first: "How can we do more for our patients? Everything at Takeda starts with this question." *See* About Takeda, TAKEDA, https://www.takeda.com/en-us/who-we-are; *see also* Takeda in the U.S., TAKEDA, https://www.takeda.com/en-us/who-we-are/company-information/company-facts ("Our unwavering commitment to putting patients first guides our scientific discovery and helps us as we strive to address unmet medical needs. Takeda's U.S. operations are integral to our global business and to bringing better health to people, brighter future to the world.").

43. Takeda is aware of the "growing trend of falsified medicines," which "deliberately misrepresent their identity, composition, or source." *Takeda's Position on Falisified Medical Products*, TAKEDA (May 2023), https://assets-dam.takeda.com/image/upload/v1684891388/legacy-dotcom/siteassets/system/who-we-are/companyinformation/positions--guidelines/Position_Falsified_Medical_Products.pdf.

44. Takeda "recognizes" that it has "an important role to play in protecting the integrity of [its] products" and represents to have taken various security measures to prevent against tampering of its products, such as "tamper evident security seals." *Id.*

45. Moreover, Takeda represents and warrants that it manufactures drugs in accordance with strict quality standards. *See, e.g.*, Ethics in quality and environment, health and safety, TAKEDA, https://www.takeda.com/about/corporate-responsibility/ethics-disclosures/ethics/ ("We use best practices for research, development and safety evaluation throughout the entire product

life cycle. . . . We monitor the safety of all our products, continuously collecting safety information in the development phase of new medicines and throughout the time they are marketed.").

46. Takeda represents that Vyvanse has six strengths of chewable tablets and seven strengths of capsules. *See Dosing & Administration for Adults*, VYVANSE, https://www.vyvanse.com/doses (last visited Jan. 24, 2024). The dosages vary between 10 and 70 milligrams with the recommended starting dose being 30 milligrams. *See id.*

47. Takeda's Vyvanse is accompanied by an FDA-approved label. By presenting consumers with an FDA-approved label, Takeda made representations and express warranties to consumers that its product was consistent with the safety, quality, purity, identity, and strength characteristics reflected in the FDA-approved labels and/or were not adulterated and/or misbranded.

48. Takeda's Vyvanse also contained patient information leaflets, which were authored by Takeda and specifically addressed to the patient consumers.

49. These medication patient information leaflets or medication guides made express warranties about Takeda's Vyvanse medication, including by identifying the active ingredient lisdexamfetamine dimesylate and addressing the benefits and potential side effects associated with taking Vyvanse containing lisdexamfetamine dimesylate.

50. By introducing Vyvanse into the United States market with the FDA-approved label identifying the milligram dosage of medication within each Vyvanse capsule, Takeda represented and warranted to physicians and end users that its medication in fact contained the amount of milligrams so indicated on its label. The end-user patients relied on this representation when purchasing and taking Vyvanse.

51. Takeda's Vyvanse capsules lacked the correct dosage of lisdexamfetamine dimesylate to treat consumers with ADHD or B.E.D. For these and other reasons, Takeda's Vyvanse capsules were dangerously adulterated and/or misbranded, and it was illegal for Takeda to have introduced them in the United States. *See, e.g.*, 21 U.S.C. §§ 331(a), 331(g), 351(a)(2)(B).

52. Adulterated and/or misbranded Vyvanse without the prescribed active ingredient is worthless. No reasonable consumer (including Plaintiff), and no downstream purchaser in the supply chain, would purchase such "medication," nor would any manufacturer knowingly market or sell capsules without the active ingredient. At a minimum, adulterated and/or misbranded Vyvanse was worth less than its non-adulterated or non-misbranded equivalents.

53. Plaintiff's September 12, 2023 prescription bottle had a label representing that the Vyvanse capsules, manufactured by Takeda, were 40 mg. In truth, the capsules were empty and contained 0 mg of the medication.

54. Supplying Plaintiff and putative class members with capsules that lacked the correct dosage of medication, as prescribed by their doctor, is highly dangerous. The side effects of not taking medication for ADHD as prescribed can lead to death. *See, e.g.*, Cecilia Garzella, *ADHD drug prices rise as Adderall shortage leaves patients scrimping to fill prescriptions*, USA TODAY (Dec. 21, 2023), https://www.usatoday.com/story/news/investigations/2023/12/21/adhd-drug-prices-increase-nationwide-shortage/71746194007/ ("'Traffic accidents are much more common in people with ADHD, and if you don't have your meds, it becomes even more dangerous.'"); Susan Scutti, *Medication slashes crash risk for ADHD, study finds*, CNN (May 10, 2017), https://www.cnn.com/2017/05/10/health/adhd-distracted-driving-study/index.html (estimating that up to 22.1% of car crashes could have been avoided if the patients with ADHD had received medication).

CLASS ACTION ALLEGATIONS

55. Plaintiff brings this action both individually and as a class action pursuant to FED. R. CIV. P. 23 against Takeda on her own behalf and on behalf of the nationwide class defined below:

> All individuals residing in the United States who paid any amount of money for and/or suffered any injury from legally prescribed and obtained Vyvanse capsules that were manufactured by Takeda and were either empty or partially empty in that there was less of the Vyvanse medication present in the capsule than indicated by Takeda.

56. Plaintiff also seeks to represent an Alabama subclass of persons defined as follows:

> All individuals residing in the State of Alabama who paid any amount of money for and/or suffered any injury from legally prescribed and obtained Vyvanse capsules within the last four years from the date of filing this action that were manufactured by Takeda and were either empty or partially empty in that there was less of the Vyvanse medication present in the capsule than indicated by Takeda.

57. Unless stated otherwise, the nationwide class and Alabama subclass are referred to collectively herein as the "class."

58. The nationwide class includes those who made a purchase within four years of the filing of this action, except as follows: for purchases made in Mississippi, South Carolina, or Wisconsin, the nationwide class includes those who made a purchase within six years of the filing of this action; for purchases made in Iowa or Oklahoma, the nationwide class includes those who made a purchase within five years of the filing of this action; and for purchases made in Colorado, Connecticut, and Massachusetts, the nationwide class includes those who made a purchase within three years of filing of this action.

59. Excluded from the class are Defendants, any entity in which Defendants have a controlling interest, any of the officers, directors, or employees of any Defendant, the legal

representatives, heirs, successors, and assigns of any Defendant, anyone employed with Plaintiff's counsel's firms, and any Judge to whom this case is assigned, and his or her immediate family.

60. The class does not include purchases made in Louisiana of Vyvanse manufactured by Takeda.

61. Plaintiff's class satisfies the numerosity, commonality, typicality, adequacy, and superiority requirements of a class action under Rule 23, as set forth more fully herein.

62. While the exact number of class members cannot be determined without discovery, there are potentially millions of Vyvanse consumers nationwide. *See, e.g.*, VYVANSE, https://www.vyvanse.com/ (last visited Feb. 2, 2024) (noting that millions of adult lives have been treated and that Vyvanse is the number one prescribed branded ADHD medication). The class members are therefore so numerous that joinder of all members is impracticable.

63. There are questions of fact and law common to the class that predominate over any questions affecting only individual members. These common questions of law and fact include but are not limited to:

a. Whether Takeda made and breached express warranties of the contents, including the dosage, of Plaintiff and class members' Vyvanse prescriptions;

b. Whether Takeda violated the Alabama Deceptive Trade Practices Act (ALA. CODE § 8-19-1, *et seq.*);

c. Whether Takeda's Vyvanse capsules lacked the represented dosage of medication;

d. Whether Takeda provided empty capsules;

e. Whether Takeda provided medication with less than the actual dosage;

f. Whether Takeda made misrepresentations and omitted material information with regards to its Vyvanse medication;

g. Whether Takeda's Vyvanse capsules were adulterated and/or misbranded;

h. Whether Takeda violated cGMPs regarding the manufacture of Vyvanse;

i. Whether the class sustained damages as a result of Takeda's conduct; and

j. Whether the class is entitled to damages as a remedy for Takeda's conduct.

64. The questions set forth above predominate over any questions affecting only individual persons, and a class action is superior with respect to considerations of consistency, economy, efficiency, fairness, and equity to other available methods for the fair and efficient adjudication of the claims asserted herein.

65. Plaintiff's claims are typical of class members' claims. Plaintiff and class members all suffered the same type of harm. Plaintiff has substantially the same interest in this matter as all other class members, and her claims arise out of the same set of facts and conduct as the claims of all other class members.

66. Plaintiff is an adequate representative of the class because she is a member of both the nationwide class and Alabama subclass and her interests do not conflict with the interests of those she seeks to represent. The interests of the class members will be fairly and adequately protected by Plaintiff and her counsel, who have extensive experience prosecuting complex class litigation.

67. A class action is the appropriate method for the fair and efficient adjudication of this controversy. Takeda has acted or refused to act on grounds generally applicable to the class. As such, preliminary and/or final injunctive relief and corresponding declaratory relief is appropriate respecting the class as a whole.

68. The presentation of separate actions by individual class members would create a risk of inconsistent and varying adjudications, establish incompatible standards of conduct for Takeda, and/or substantially impair or impede the ability of class members to protect their interests.

69. It would be impracticable and undesirable for each member of the class who suffered harm to bring a separate action. In addition, the maintenance of separate actions would place a substantial and unnecessary burden on the courts, which could result in inconsistent adjudications while a single action can determine, with judicial economy, the rights of all class members.

COUNT I: BREACH OF EXPRESS WARRANTY
(As Adopted by the Uniform Commercial Code Provisions of Each State)
(On Behalf of the Nationwide Class, Excluding Louisiana)

70. Plaintiff incorporates and restates by reference all of the foregoing allegations as though fully set forth herein.

71. Plaintiff, and each member of the class, formed a contract with Takeda at the time Plaintiff and the other class members purchased Vyvanse. The terms of the contract include the promises and affirmations of fact made by Takeda on the Vyvanse packaging and through marketing and advertising, including that the capsules were safe and effective and would contain the prescribed dosage of lisdexamfetamine dimesylate. This labeling, marketing, and advertising constitute express warranties and became part of the basis of the bargain, and are part of the standardized contract between Plaintiff and the members of the class and Takeda.

72. Plaintiff and each member of the class are also the intended third-party beneficiary recipients of all contracts between Takeda and any downstream wholesalers or retail pharmacies

that ultimately sold the empty and partially empty Vyvanse capsules to Plaintiff and putative class members.

73. Plaintiff and each member of the putative class are the persons for whose direct benefit any promises were made in the contracts that included express warranties between Takeda and any downstream wholesalers or retail pharmacies. Takeda intended to warrant its product to end users, such as Plaintiff and putative class members, who are the ones that ultimately ingested Takeda's products.

74. Takeda expressly warranted that its Vyvanse drug was fit for its ordinary use, i.e., as an FDA-approved central nervous system stimulant prescription medication containing lisdexamfetamine dimesylate and used in the treatment of ADHD in adults and children as well as B.E.D. in adults.

75. Takeda sold Vyvanse that it expressly warranted as having a specified dosage of lisdexamfetamine dimesylate and as not being adulterated or misbranded.

76. Takeda's Vyvanse capsules did not conform to its express representations and warranties because the product did not contain the represented dosage and was adulterated and misbranded.

77. Takeda's Vyvanse capsules were goods that were meant to be consumed.

78. At the time that Takeda marketed and sold Vyvanse, it recognized the purposes for which its product would be used, and expressly warranted its capsules as having a specified milligram dosage of lisdexamfetamine dimesylate and that its product was not adulterated or misbranded. These affirmative representations became part of the basis of the bargain in every purchase by Plaintiff and other class members.

79. Plaintiff and each member of the class are natural persons who are reasonably expected to use, consume, or be affected by the adulterated and/or misbranded Vyvanse manufactured and sold by Takeda.

80. Takeda breached its express warranty with respect to its Vyvanse capsules as they were not of merchantable quality, were not fit for their ordinary purpose, and were adulterated and misbranded.

81. Plaintiff and each member of the class would not have purchased Vyvanse had they known these drugs did not contain the represented dosage of lisdexamfetamine dimesylate.

82. As a direct and proximate result of Takeda's breach of express warranty, Plaintiff and other class members have been injured and suffered damages including, but not limited to, the amount of the purchase price of their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases, in that the Vyvanse they purchased was so inherently flawed, unfit, or unmerchantable as to have no market value.

83. Plaintiff's claim for breach of express warranty is based solely on the provisions of the Uniform Commercial Code as codified and adopted by each State (with the exception of Louisiana). Plaintiff brings no claims based on federal law.

COUNT II: VIOLATION OF THE ALABAMA DECEPTIVE TRADE PRACTICES ACT
(ALA. CODE § 8-19-1, *et seq.*)
(On Behalf of the Alabama Subclass)

84. Plaintiff incorporates and restates by reference all of the foregoing allegations as though fully set forth herein.

85. The Alabama Deceptive Trade Practices Act (ADTPA) prohibits the following conduct in trade or commerce:

> (5) Representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or qualities that they do not have . . . .
>
> (6) Representing that goods are original or new if they are deteriorated, reconditioned, reclaimed, used, secondhand, or altered to the point of decreasing their value or rendering the goods unfit for the ordinary purpose for which they were purchased, provided that this subdivision shall not apply to new goods which have been reconditioned, reclaimed, or repaired and such fact is disclosed to the purchaser.
>
> (7) Representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another.
>
> (9) Advertising goods or services with intent not to sell them as advertised.
>
> (27) Engaging in any other unconscionable, false, misleading, or deceptive act or practice in the conduct of trade or commerce.

ALA. CODE § 8-19-5. Takeda knowingly violated each of these subsections.

86. Takeda's acts and omissions affect trade and commerce in Alabama.

87. Plaintiff and putative Alabama subclass members purchased Vyvanse for personal, family, or household use.

88. Takeda, through a pervasive pattern of unfair, false, and misleading statements and omissions manufactured and/or sold Vyvanse capsules without revealing to consumers that the products lacked, or contained less of, the active ingredient lisdexamfetamine dimesylate despite representations that the capsules contained a specified milligram dosage of the medication. Takeda also failed to reveal to consumers that its capsules did not comply with cGMPs and/or were adulterated and/or misbranded.

89. In addition to these material omissions, Takeda affirmatively and deceptively misrepresented material facts including, inter alia, that its capsules contained a specified dosage of lisdexamfetamine dimesylate, that its capsules containing lisdexamfetamine dimesylate offered various benefits and posed potential side effects, that its capsules containing lisdexamfetamine

dimesylate could be used to treat ADHD and B.E.D., and that it manufactures its drugs in accordance with strict quality standards. These misrepresentations were present on, among other things, the Vyvanse labels, the patient package inserts, medication guides, instructions for use, and Takeda's websites.

90. Takeda's misrepresentations and omissions were material to Plaintiff and putative Alabama subclass members' transactions and were made knowingly or with reason to know that Plaintiff and putative Alabama subclass members would rely on the misrepresentations and omissions. Had Plaintiff and putative Alabama subclass members known that the Vyvanse capsules lacked lisdexamfetamine dimesylate or did not contain the represented dosage of lisdexamfetamine dimesylate, i.e. the dosage prescribed to Plaintiff and putative Alabama subclass members by their doctor, they would not have purchased them.

91. Plaintiff and putative Alabama subclass members reasonably relied on Takeda's misrepresentations and omissions and suffered harm as a result. Among the injuries suffered, Plaintiff and putative Alabama subclass members overpaid for the Vyvanse capsules and did not receive the benefit of their bargain. These injuries are the direct and natural consequence of Takeda's misrepresentations and omissions.

92. Plaintiff reserves the right to allege further conduct that constitutes other unlawful business acts or practices as such conduct is ongoing and continues to this date.

93. Plaintiff and putative Alabama subclass members seek actual and statutory damages to the fullest extent permitted under applicable law.

94. Plaintiff and putative Alabama subclass members also seek injunctive relief to benefit the general public by bringing an end to Takeda's deceptive business practices described herein which threaten future injury to the general public. Specifically, an injunction requiring

Takeda to implement reasonable manufacturing protocols that test for the accuracy of lisdexamfetamine dimesylate present in its Vyvanse capsules.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, requests relief as follows:

(1) an order certifying this case as a class action under FED. R. CIV. P. 23 and appointing Plaintiff as class representative and undersigned counsel as class counsel to represent the class;

(2) compensatory damages in an amount to be proven at trial;

(3) statutory damages as provided for in the Uniform Commercial Code adopted by each State (with the exception of Louisiana) and the Alabama Deceptive Trade Practices Act, including multiple damages to Plaintiff and the Class;

(4) injunctive relief;

(5) costs of suit, including reasonable attorneys' fees, expenses, and costs;

(6) pre- and post-judgment interest at the maximum rate allowed by law; and

(7) such other legal and equitable relief as the Court deems proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues so triable.

//

//

//

//

Dated: March 5, 2024

Respectfully submitted,

/s/ Patrick T. Egan

Patrick T. Egan (BBO #637477)
BERMAN TABACCO
One Liberty Square
Boston, MA 02109
Telephone: (617) 542-8300
Facsimile: (617) 542-1194
pegan@bermantabacco.com

Robert G. Methvin, Jr.
(*to be admitted pro hac vice*)
James M. Terrell
(*to be admitted pro hac vice*)
Courtney C. Gipson
(*to be admitted pro hac vice*)
METHVIN, TERRELL, YANCEY, STEPHENS & MILLER, P.C.
2201 Arlington Avenue South
Birmingham, Alabama 35205
Telephone: (205) 939-0199
Facsimile: (205) 939-0399
rgm@mtattorneys.com
jterrell@mtattorneys.com
cgipson@mtattorneys.com